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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,653	01/22/2004	Leonard Schlessinger	8223.002.CPUS02	8542

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HOUSTON, TX 77002

EXAMINER
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SIMS, JASON M

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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03/11/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/763,653	<b>Applicant(s)</b> SCHLESSINGER ET AL.	
	<b>Examiner</b> JASON M. SIMS	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10,31-40,52 and 61-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10,31-40,52 and 61-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/20/2007 has been entered.

Claims 1-10, 31-40, 52, and 61-75 are the current claims hereby under examination.

#### ***Claim Rejections - 35 USC § 101***

##### ***Response to Arguments:***

Applicant's arguments, filed 12/20/2007, with respect to rejection of claims under 35 USC 101 have been fully considered and are persuasive because of applicant's amendments. Therefore the rejection has been withdrawn.

#### ***Claim Rejections - 35 USC § 112***

##### ***Response to Arguments:***

Applicant's arguments, filed 12/20/2007, with respect to rejections of claims under 35 USC 112 second paragraph have been fully considered and are persuasive because of applicant's amendments and arguments. Therefore the rejections have been withdrawn.

**The following are rejections being newly made:**

Art Unit: 1631

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 7, 10, 33, 40, 66, 70, and 73 and all claims dependent therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 7, 10, 33, 40, 66, 70, and 73 and all claims dependent therefrom comprise the term  $DF_2$ , which is defined in claim 4 as representing an incidence of disease. However the specification defines the instant term as representing “causes of diabetes.” Therefore, it is unclear as to what exactly one is to plug into this equation and it is vague and indefinite as how this term represents incidence of diabetes. Clarification via clearer claim wording is required.

Claims 3, 8, 9, 33, 38, 39, 40, 66, 71, 72, and 75 all comprise the variables either a and b or a, b, c, and d and define them as being set to fit data for a population, which has been deemed as vague and indefinite. It is unclear as to which population these values are being set to, such as a virtual population or real population and how they are being fit. It is unclear from the specification as to how the instant variables or which method is being used for said fitting of said variables. Clarification via clearer claim wording is required.

Claims 4, 34, and 67 and all claims dependent therefrom comprise  $xi_{sub.3}$  and  $xi_{sub.2}$  in the equation whereas the claim language addresses  $xi_{sub.1}$  and  $xi_{sub.3}$ ,

which causes said claims to be vague and indefinite. Clarification via clearer claim wording is required.

Claims 4, 34, and 67 and all claims dependent therefrom comprise the wording “randomizing the virtual patient within the population,” which has been deemed as vague and indefinite. It is unclear as to how the patient is randomized within the population or what method is being referred by the wording “randomizing the virtual patient within the population.” Clarification via clearer claim wording is required.

Claims 6, 36, and 69 and all claims dependent therefrom comprise xi.sub.3, which is vague and indefinite as to whether this is the same xi.sub.3 as in claims 4, 34, and 67. Clarification via clearer claim wording is required.

Claims 10, 40, and 73 and all claims dependent therefrom comprise the variable I or 1, which is vague and indefinite. If the equation comprises the number 1 it is unclear as to what purpose it serves and if the equation comprises the variable I, then it is unclear as to what value or meaning this variable has and how it is determined in said equations. Clarification via clearer claim wording is required.

Claims 5, 35, and 68 comprise the variables a,b,c,and d to calculate RBMI. It is unclear as to whether these are the same variables, which have all been set to fit data or if their values are determined differently. Clarification via clearer claim wording is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 31-32, 52, 61, 63, 65, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Holde (1996).

The claims are drawn to a method for estimating a virtual patient's fasting plasma glucose level, comprising: determining the virtual patient's basal hepatic production; determining the virtual patient's insulin level; calculating the virtual patient's fasting blood glucose at time  $t$  by solving an equation where the virtual patient's fasting blood glucose level at time  $t$  is equal to the basal hepatic production divided by the insulin level and efficiency of insulin use.

Van Holde (1996) at page 824-825 teaches the role of insulin in the blood. Van Holde (1996) teaches one of the roles of insulin is to promote the uptake of fuel substances into some cells, such as increased uptake of glucose out of the blood and into muscle and adipose tissue and also activation of glycolysis in the liver. Van Holde

Art Unit: 1631

(1996) at page 826-827 further teaches the relationship between blood glucose levels and insulin levels, such as if you increase insulin levels then blood glucose levels decrease and vice versa under normal circumstance. Van Holde (1996) clearly teaches under normal circumstances that insulin and glucose have an indirect mathematical relationship.

Van Holde (1996) does not explicitly teach calculating the level of blood glucose according to the equation as is instantly claimed.

It would have been obvious to one of ordinary skill in the art to mathematically represent the calculation of a fasting blood glucose level as being indirectly proportionate to the level of insulin as Van Holde (1996) has clearly described in the recited pages. It has been well known by those of ordinary skill in the art that under normal circumstances, if one increases the level of insulin in the blood that its effect is to decrease the glucose level in the blood. It is common to those of ordinary skill in the art to represent such relationships generically and mathematically as an indirect relationship. Furthermore, under normal circumstances insulin will work as predicted and therefore its efficiency will not be altered. Therefore, to represent efficiency as a value of 1, under normal circumstances, would have been obvious to one of ordinary skill in the art and the results would have been unobvious and predictable.

Van Holde (1996) does not explicitly teach having the efficiency value for insulin in the presence of diabetes somewhere between 0-1.

Van Holde (1996) at page 829 teaches that there may be several reasons for the cause of diabetes, such as a mutation in the insulin structure or mutations in the insulin

Art Unit: 1631

receptors or molecules involved in the conversion of molecules into insulin all of which effect the efficiency of role of insulin. Therefore, to represent the efficiency of insulin under said conditions, it would have been obvious to one of ordinary skill in the art to represent the efficiency of insulin as somewhere between 0-1 depending on the condition and cause and the results would have been unobvious and predictable.

Van Holde (1996) does not specifically teach saving at least one value to a computer storage device.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to store a calculated value to a computer storage device because it is the common practice of those in the field to use computers to perform such calculations and saving a result is common practice to those in the field and would not have produced any unobvious or unpredictable results by doing so.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.



Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

/Michael Borin, Ph.D./  
Primary Examiner, Art Unit 1631